

**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

| | |
|------------------------|------------------|
| Application Number | 09/929,818 |
| Filing Date | August 13, 2001 |
| First Named Inventor | L land F. WILSON |
| Art Unit | 1654 |
| Examiner Name | Billy D. CHISM |
| Attorney Docket Number | 9050-0013.24 |

ENCLOSURES (Check all that apply)

- | | | |
|---|--|---|
| <input type="checkbox"/> No fee due <input type="checkbox"/> Fee Transmittal <input checked="" type="checkbox"/> Fee(s) due <input checked="" type="checkbox"/> Fee Transmittal <input checked="" type="checkbox"/> Check for \$55.00 <input checked="" type="checkbox"/> Charge any underpayment or credit any overpayment to Deposit Account No. 18-0580 <input checked="" type="checkbox"/> Return postcard <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input checked="" type="checkbox"/> One-month Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement & Form(s) PTO-1449 <input type="checkbox"/> Copy(ies) of cited reference(s) <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts / Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation, Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s): | <input type="checkbox"/> After Allowance Communication to a Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <u>Response to Restriction Requirement.</u> |
|---|--|---|
- Remarks:
The Commissioner is hereby authorized to charge any additional or underpayment of fee(s) to Deposit Account No. 18-0580.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|--------------------------------------|--|-----------|------------------|
| Firm or Individual Name (print/type) | Karen Canaan, Registration No. 42,382 Reed & Eberle LLP | Telephone | (650) 330-0900 |
| Signature | | Date | January 20, 2004 |

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

| | | | |
|-------------------|----------------------|------|------------------|
| Name (print/type) | Margaret K. Surridge | Date | January 20, 2004 |
| Signature | | Date | January 20, 2004 |



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**FEE TRANSMITTAL
for FY 2004**

Effective 10/01/03. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** \$55.00**Complete if Known**

Application Number 09/929,818

Filing Date August 13, 2001

First Named Inventor Leland F. WILSON

Examiner Name Billy D. CHISM

Group Art Unit 1654

Attorney Docket No. 9050-0013.24

METHOD OF PAYMENT (check all that apply)☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:

Deposit Account No. 18-0580

Deposit Account Name Reed & Eberle LLP

The Commissioner is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Charge any underpayment or credit any overpayments☐ Charge any additional fee(s) during the pendency of this application☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

| Large Entity | | Small Entity | | Fee Description | Fee Paid |
|--------------|----------|--------------|----------|------------------------|----------|
| Fee Code | Fee (\$) | Fee Code | Fee (\$) | | |
| 1001 | 770 | 2001 | 385 | Utility filing fee | |
| 1002 | 340 | 2002 | 170 | Design filing fee | |
| 1003 | 530 | 2003 | 265 | Plant filing fee | |
| 1004 | 770 | 2004 | 385 | Reissue filing fee | |
| 1005 | 160 | 2005 | 80 | Provisional filing fee | |

SUBTOTAL (1) \$0**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

| Total Claims | | Extra Claims | | Fee from below | | Fee Paid |
|---------------------------|----|--------------|---|----------------|---|----------|
| Independent Claims | 40 | - 20** = | 0 | x | 0 | 0 |
| Multiple Dependent Claims | 9 | - 3** = | 0 | x | 0 | 0 |
| | | | | | 0 | 0 |

| Large Entity | | Small Entity | | Fee Description |
|--------------|----------|--------------|----------|--|
| Fee Code | Fee (\$) | Fee Code | Fee (\$) | |
| 1202 | 18 | 2202 | 9 | Claim in excess of 20 |
| 1201 | 86 | 2201 | 43 | Independent claims in excess of 3 |
| 1203 | 290 | 2203 | 145 | Multiple dependent claim, if not paid |
| 1204 | 86 | 2204 | 43 | ** Reissue independent claims over original patent |
| 1205 | 18 | 2205 | 9 | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) \$0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

| Large Entity | | Small Entity | | Fee Description | Fee Paid |
|--------------|----------|--------------|----------|--|----------|
| Fee Code | Fee (\$) | Fee Code | Fee (\$) | | |
| 1051 | 130 | 2051 | 65 | Surcharge - late filing fee or oath | |
| 1052 | 50 | 2052 | 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 | 130 | 1053 | 130 | Non-English specification | |
| 1812 | 2,520 | 1812 | 2,520 | For filing a request for ex parte reexamination | |
| 1804 | 920* | 1804 | 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1,840* | 1805 | 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 | 110 | 2251 | 55 | Extension for reply within first month | \$55.00 |
| 1252 | 420 | 2252 | 210 | Extension for reply within second month | |
| 1253 | 950 | 2253 | 475 | Extension for reply within third month | |
| 1254 | 1,480 | 2254 | 740 | Extension for reply within fourth month | |
| 1255 | 2,010 | 2255 | 1,005 | Extension for reply within fifth month | |
| 1401 | 330 | 2401 | 165 | Notice of Appeal | |
| 1402 | 330 | 2402 | 165 | Filing a brief in support of an appeal | |
| 1403 | 290 | 2403 | 145 | Request for oral hearing | |
| 1451 | 1,510 | 1451 | 1,510 | Petition to institute a public use proceeding | |
| 1452 | 110 | 2452 | 55 | Petition to revive - unavoidable | |
| 1453 | 1,330 | 2453 | 665 | Petition to revive - unintentional | |
| 1501 | 1,330 | 2501 | 665 | Utility issue fee (or reissue) | |
| 1502 | 480 | 2502 | 240 | Design issue fee | |
| 1503 | 640 | 2503 | 320 | Plant issue fee | |
| 1460 | 130 | 1460 | 130 | Petitions to the Commissioner | |
| 1807 | 50 | 1807 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 180 | 1806 | 180 | Submission of Information Disclosure Stmt | |
| 8021 | 40 | 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 770 | 2809 | 385 | Filing a submission after final rejection (37 CFR § 1.129(a)) | |
| 1810 | 770 | 2810 | 385 | For each additional invention to be examined (37 CFR § 1.129(b)) | |
| 1801 | 770 | 2801 | 385 | Request for Continued Examination (RCE) | |
| 1802 | 900 | 1802 | 900 | Request for expedited examination of a design application | |

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) \$55.00**SUBMITTED BY**

Name (Print/Type) Karen Canaan

Registration No. (Attorney/Agent) 42,382

Telephone

Complete (if applicable)

(650) 330-0900

Signature

Date

January 20, 2004



Atty Dkt No. 9050-0013.24
Serial No. 09/929,818

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Leland F. WILSON et al.

Confirmation No.: 9897

Serial No.: 09/929,818

Group Art Unit: 1654

Filing Date: August 13, 2001

Examiner: Billy D. CHISM

Title: TREATMENT OF FEMALE SEXUAL DYSFUNCTION WITH VASOACTIVE AGENTS, PARTICULARLY VASOACTIVE INTESTINAL POLYPEPTIDE AND AGONISTS THEREOF

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This communication responds to the Restriction Requirement, mailed December 3, 2003, for this matter. In addition, applicants hereby request a one-month extension of time to respond, extending the due date to February 3, 2004. A check to cover the required extension fee is enclosed. The Examiner is requiring restriction of the application to one sequence from the following two sets:

Set I: inventions 1-204, claims 1-28, drawn to a method of treating female sexual disorders comprising administering any one of SEQ ID NOs: 2-205; and

Set II: inventions 205-408, claims 29-40, drawn to polypeptide compositions comprising any one of amino acid sequences of SEQ ID NOs: 2-205.

In the response, applicants elect SEQ ID NO: 2 from Set I for examination. This election is made with traverse.

In the Office Action, the Examiner provides that if it can be demonstrated that a single subsequence within a specific sequence can be searched, then the subsequence may be searched and all sequences including the subsequence may be searched.

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Applicants acknowledge the Examiner's request with respect to the VIP agonists as claimed but traverse the Examiner's restriction on the grounds that it does not include the endogenous VIP of SEQ ID NO: 1. On this matter, applicants note that independent claim 1 of the present invention claims the following:

1. A method for treating sexual dysfunction in a female individual, comprising administering to the vagina and/or vulvar region of the individual a pharmaceutical formulation that comprises *a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive intestinal polypeptide and agonists thereof.*

At page 14 of the specification, the amino acid sequence for endogenous human vasoactive intestinal polypeptide ("VIP") is provided as follows:

H-S-D-A-V-F-T-D-N-Y-T-R-L-R-K-Q-M-A-V-K-K-Y-L-N-S-I-L-N (SEQ. ID NO. 1)
1 5 10 15 20 25 29

At page 13 of the specification, it is explained that analogs of VIP, also called VIP agonists, are VIP sequences wherein one or more of the amino acids has been substituted. For example, for a VIP agonist sequence such as SEQ. ID NO. 2, [Lys¹², Nle¹⁷]-VIP represents the endogenous VIP sequence with Lys replacing threonine (T) at position 12 and norleucine replacing glutamine (Q) at position 17.

Referring back to claim 1, it is noted that the claim recites a Markush group consisting of endogenous VIP or VIP agonists, with the latter encompassing SEQ ID NOs. 2-205.

In the Restriction Requirement, the Examiner does not permit applicant to choose between endogenous VIP and VIP analogs for practicing the claimed invention; rather, the Examiner only requires applicant to choose one VIP analog among the 204 identified sequences. Applicants submit that because the endogenous VIP and VIP agonists of the claimed invention represent a Markush group, a proper restriction would require election of one invention from an additional set directed to the methods and compositions of the claimed invention including only SEQ ID NO: 1, i.e., endogenous VIP.

Were the Examiner to adopt such a restriction requirement, applicants would choose to pursue prosecution of the claimed method and compositions of claims 1-40 for endogenous VIP and not one of the 204 recited VIP agonists. On this matter, applicants submit that with the election of endogenous VIP, there would be no undue burden placed on the Examiner to examine both the method and composition claims for this application. Notwithstanding the foregoing, upon election of endogenous VIP, should the

Examiner deem that further restriction between the method and composition claims is necessary, applicants elect method claims 1-28.

In light of the foregoing, applicants respectfully request that the Examiner change the Restriction Requirement so that it requires applicants to elect between:

Set I: claims 1-28, drawn to methods for treating female sexual disorders comprising administering a VIP agonist from any one of SEQ ID NOs: 2-205.

Set II: claims 29-40, drawn to polypeptide compositions comprising a VIP agonist having an amino acid sequence from any one of SEQ ID NOs: 2-205.

Set III: claims 1-40, drawn to methods and polypeptide compositions for treating female sexual disorders comprising endogenous VIP (SEQ ID NO: 1).

In response, applicants elect Set III, claims 1-40, SEQ. ID NO: 1. Should the Examiner require further restriction of the claims of Set III so that applicant is required to choose between method claims 1-28 and compositions claims 29-40, applicants elect method claims 1-28.

As an additional matter concerning the election of SEQ ID NO: 2, applicants further suggest to the Examiner that both SEQ ID NO: 2 and SEQ ID NO: 3 should be examined together as no additional burden would be placed on the Examiner by including SEQ ID NO: 3 in the search of SEQ ID NO: 2. Directing the Examiner's attention to page 13 of the specification, lines 11-13, it is explained therein, that the only difference between SEQ ID NO: 2 and SEQ ID NO: 3 is that SEQ ID NO: 3 is that the hydrogen at the N-terminus of the sequence of SEQ ID NO: 2 is replaced with an acetyl group. Aside from that, the sequence of SEQ ID NO: 2 and the sequence of SEQ ID NO: 3 are identical. Accordingly, when examining SEQ ID NO: 2 and SEQ ID NO: 3, the same amino acid sequence would be searched; the only difference between the full-length sequence of SEQ ID NO: 2 and SEQ ID NO: 3 would be whether there is a hydrogen or an acetyl group at the N-terminus. Applicants submit that such a difference is not sufficient to make SEQ ID NO: 2 and SEQ ID NO: 3 patentably distinct.

With this election, applicants reserve the right to pursue all non-elected subject matter in one or more divisional applications.

In closing, applicants respectfully request that the Examiner consider the revised restriction of this application as set forth herein. Should the Examiner refuse to adopt applicants suggested restriction, applicants submit that this response is nonetheless responsive to the Restriction Requirement under reply and consequently, upon entry of this response, prosecution on the merits of this application should be initiated.

If the Examiner has any questions concerning this communication, he is encouraged to contact the undersigned attorney at (650) 330-4913 or at canaan@reedpatent.com.

Respectfully submitted,

By:

A handwritten signature in black ink, appearing to read "Karen Canaan", written over a horizontal line.

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